K092548 1/2

DEC 15 2009

510(k) Summary of Safety and Effectiveness:

EXTREMITY MEDICAL Implant System

Submitter:	EXTREMITY MEDICAL LLC 300 Interpace Parkway Suite 410 Parsippany, NJ 07054
Contact Person	Jamy Gannoe President Phone: 973-588-8980 Email: jgannoe@extremitymedical.com
Date Prepared	August 18, 2009
Trade Name	EXTREMITY MEDICAL Trapezium Prosthesis
Classification Name and Number	Wrist joint carpal trapezium polymer prosthesis 21 CFR 888.3770
Product Code	KYI
Predicate Devices	Wright Medical, Metallic CMC Spherical Implant K960534 Wright Medical, Orthosphere Ceramic Spherical Implant, K030319 Wright Medical, Swanson Titanium Carpal Scaphoid Implant, K864490 Wright Medical, Swanson Titanium Carpal Lunate Implant, K864491 Wright Medical, TIE-IN Trapezium, K033529 Wright Medical, Trapezium Implant, K781756 Ascension Orthopedics, PyroSphere, K042690 Ascension Orthopedics, PyroCarbon Lunate, K080997
Device Description	The EXTREMITY MEDICAL Trapezium Prosthesis

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Indications for use	The Extremity Medical Trapezium Prosthesis is indicated for use in degenerative or post-traumatic (e.g. following an old Bennett fracture) disabilities of the thumb basal joint with: - Localized pain and palpable crepitation at the base of the thumb on the "grind test" (circumduction with axial compression of the thumb) - Decreased motion, pinch, and grip strength - X-ray evidence of arthritic changes of the trapeziometacarpal, trapezioscaphoid, trapeziotrapezoid, and trapezium-second metacarpal joints, singly or in combination. - Associated unstable, stiff, or painful distal joints of thumb or swan neck deformity
Statement of Technological Comparison	The EXTREMITY MEDICAL Trapezium Prosthesis and its predicate devices have a similar design, and are made of the similar materials.
Conclusion	The EXTREMITY MEDICAL Trapezium Prosthesis is substantially equivalent to its predicate devices. This conclusion is based upon the fact that this device is substantially equivalent in terms of indications for use, materials, design and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC 15 2009

EXTREMITY MEDICAL LLC
% Mr. Jamy Gannoe
300 Interpace Parkway
Suite 410
Parsippany, NJ 07054

Re: K092548
Trade/Device Name: Extremity Medical Trapezium Prosthesis
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: II
Product Code: KYI
Dated: November 19, 2009
Received: November 23, 2009

Dear Mr. Gannoe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092548

Device Name: EXTREMITY MEDICAL TRAPEZIUM PROSTHESIS

Indications for Use:

The Extremity Medical Trapezium Prosthesis is indicated for use in degenerative or post-traumatic (e.g. following an old Bennett fracture) disabilities of the thumb basal joint with:

- Localized pain and palpable crepitation at the base of the thumb on the "grind test" (circumduction with axial compression of the thumb)
- Decreased motion, pinch, and grip strength
- X-ray evidence of arthritic changes of the trapeziometacarpal, trapezioscaphoid, trapeziotrapezoid, and trapezium-second metacarpal joints, singly or in combination.
- Associated unstable, stiff, or painful distal joints of thumb or swan neck deformity

Prescription Use X **AND/OR** **Over-the-counter** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092548